

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE: NATIONAL PRESCRIPTION
OPIATE LITIGATION

) CASE NO.: 1:17MD2804
)
) JUDGE DAN A. POLSTER
)
) RESPONSE OF THE DEPARTMENT
) OF JUSTICE AND DRUG
) ENFORCEMENT ADMINISTRATION
) REGARDING ARCOS DATA AND
) SUSPICIOUS ORDER REPORTS

Pursuant to the Court’s June 24, 2019 Order (ECF No. 1725), the United States Department of Justice (DOJ) and the Drug Enforcement Administration (DEA) (collectively, the “United States”) hereby submit this Response to the position papers concerning the Protective Orders governing the ARCOS data and Suspicious Order Reports (SORs). Specifically, the United States responds to the Position Paper of Media Intervenors, which urges the Court to “lift entirely” the current Protective Orders. ECF No. 1808, PageID # 52863. Media Intervenors would allow public disclosure of all ARCOS data and SORs produced in litigation discovery except in those very limited circumstances where the DEA can demonstrate by “compelling evidence” that a “particular piece of data” relates to a “specific, current ongoing investigation” and further that disclosure of each piece of data would “materially jeopardize that specific, current investigation.” ECF No. 1808, PageID # 52864. Publication of ARCOS data and SORs, even those that may not relate to an ongoing investigation, risks immediate, concrete harm to law enforcement and public interests that outweigh the interests in favor of disclosure. Media Intervenors’ proposal fails to address these harms, and moreover would require the DEA to undertake an unduly burdensome review that would divert resources from mission-critical activities. For the reasons set forth in more detail below, ample “good cause” exists under Fed.

R. Civ. P. 26(c) and the reasoning of the Sixth Circuit's opinion in *In re: National Prescription Opiate Litig.*, -- F.3d---, 2019 WL 2529050 (6th Cir. 2019), to maintain certain protections over the ARCOS data through a modified Protective Order reflecting input of all parties and to maintain the current protections over the SORs.

1. The Court Should Reject Media Intervenor's Proposal to Lift the Protective Orders Governing the ARCOS Data.

As to the ARCOS data, the Media Intervenor's brief understates both the burden on the DEA and the harm that would result if the Court were to accept the Intervenor's proposal to lift the Protective Orders. These harms and burdens establish "good cause" and favor nondisclosure, as set forth in the Sixth Circuit's opinion, 2019 WL 2529050 at *8. The harms resulting from publication of the ARCOS data, even if redacted, together with the burden of redacting the data, are significant and outweigh the interest in disclosure for at least the following reasons.

First, as this Court acknowledged in its June 24, 2019 Order, publication of the totality of the ARCOS data with redactions corresponding to specific, ongoing investigations, would "only serve to tip the DEA's hand." ECF No. 1725, Page ID # 5129. This harm is not a "stretch," as asserted by Media Intervenor (ECF No. 1808, PageID # 52864); all a drug manufacturer or distributor would need to do to determine which, if any, of its transactions are potentially under investigation by the DEA would be to compare its own records against ARCOS data made publicly available. Where an investigation is covert, such disclosure could compromise the integrity of the investigation or otherwise disadvantage the DEA in its efforts to identify wrongdoing.

Second, even if it were useful for the DEA to review the ARCOS data to redact portions related to ongoing investigations, it would be extremely burdensome for the DEA to do so. The particular lines of ARCOS data that would require redaction are not, as the Media Intervenor

assert, at the DEA's "fingertips" (ECF No. 1808, Page ID #52865), but would require an extensive review to identify. Thousands of ARCOS records would need to be manually compared against records of open investigations that the DEA may be conducting out of any of its 222 domestic offices in 23 divisions across the country. This labor-intensive review would need to be conducted by the very same DEA personnel whose primary function is the investigation of wrongdoing, thereby diverting them from their mission critical responsibilities.

Third, the ARCOS data in its current, raw form, is of limited use to the general public and may even be confusing if disclosed. The ARCOS system includes hundreds of millions of transaction records reported by DEA's numerous registrants. The DEA performs quality control over data. This includes validation checks that do not allow a transaction to proceed until errors are corrected. However, this validation process cannot identify, for example, incorrectly reported NDC Numbers, package sizes, or inaccurate quantities that registrants report to DEA. Therefore, before DEA relies on any subset of such data, it will typically conduct additional vetting of that particular subset of data it intends to analyze or use. These inherent limitations of the ARCOS data were explained to the plaintiffs so that they could take this into account in their analysis. However, others who may obtain the ARCOS data would receive no such explanation and would have no way of identifying or addressing any inaccuracies in the data. This limitation undermines the benefits Media Intervenors contend favor disclosure. What is more, such inaccuracies make the raw data potentially confusing to the general public; for example, the data could result in public scrutiny of transactions (and the parties to those transactions) that may appear suspicious but were merely erroneously recorded.

Fourth, it is critical that the Court consider the DEA's dual roles as a law enforcement agency and a regulator. With respect to the latter, it is imperative that DEA registrants — the

vast majority of which are not parties to this lawsuit — have confidence that the agency will appropriately maintain the data that the agency is required, by law, to obtain and maintain.

After considering the harm that the disclosure of raw, uncorrected ARCOS data could cause, both in terms of undermining ongoing DEA investigations and potentially confusing or misleading the public, there is “good cause” not to lift the ARCOS Protective Orders entirely as recommended by Media Intervenors. Instead, the United States believes there is a better approach to balancing the relevant interests, and requests that the Court allow the DEA, Plaintiffs, Defendants, and the Media Intervenors to meet and confer toward a modified Protective Order.

2. The Court Should Reject Media Intervenors’ Proposal to Lift the Protective Order Governing the SORs.

The United States also opposes Media Intervenor’s proposal to lift entirely the Protective Order governing the SORs. Notably, the Sixth Circuit’s opinion does not address or require this Court to revisit the Protective Order governing the SORs. Public disclosure of the SORs, including those that may not relate to a specific ongoing DEA investigation, would be harmful to law enforcement and public interests and burdensome to the DEA for the following reasons, which together constitute ample good cause under Fed. R. Civ. P. 26(c) to maintain the current Protective Order.

First, public disclosure of SORs, including the SORs that are not under investigation, would educate would-be wrongdoers about drug manufacturers’ and distributors’ practices for detecting and reporting potential misconduct and the DEA’s priorities or areas of concentration. This information may enable wrongdoers to structure illicit transactions in a manner that avoids detection and enforcement. This risk would compound the law-enforcement harm the Court has

already identified, that “public revelation of SORs could ‘tip off’ a pharmacy that it is likely the subject of an ongoing investigation by the DEA.” ECF No. 1725, Page ID #51630.

Second, public disclosure of SORs that are not under investigation would reveal the names of individuals and entities associated with transactions that were initially identified as suspicious but later determined to involve no wrongdoing. This, in turn, could subject those innocent individuals or entities unfairly to public scrutiny. Given that distributors did not follow a uniform process for identifying suspicious order and, at times, certain distributors appear to have reported all orders above a certain threshold size, regardless as to whether there was an indicia of actual suspicion, this concern is particularly acute.

Third, as with the ARCOS data, reviewing and redacting the SORs for references to current, ongoing investigations would involve an unduly burdensome review. The DEA would be required to cross-reference each of the thousands of SORs produced in discovery against all of DEA’s ongoing investigations to identify appropriate redactions, a manual process that would require coordination across multiple of DEA’s field offices and headquarters and divert resources from the DEA’s law enforcement mission.

3. Conclusion

Based on the foregoing, this Court should not lift entirely the Protective Orders governing the ARCOS data and SORs as proposed by the Media Intervenors. As to the ARCOS data, if the Sixth Circuit opinion is unchanged at the time that the mandate issues, the United States respectfully requests an opportunity to meet and confer with the Plaintiffs, Defendants, and Media Intervenors toward a modified Protective Order that balances all relevant interests. As to the SORs, the United States respectfully requests that the current Protective Orders remain in place for good cause stated herein.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on July 12, 2019, a copy of the foregoing *Response of the Department of Justice Drug Enforcement Administration Regarding ARCOS Data and Suspicious Order Reports* was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

/s/ Lynne H. Buck
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CERTIFICATE OF COMPLIANCE

Pursuant to Local Rule 7.1(f), undersigned counsel hereby certifies that the foregoing *Response of the Department of Justice Drug Enforcement Administration Regarding ARCOS Data and Suspicious Order Reports* Order is six (6) pages in length and within the limitations set by the Court's Order.

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